

# Two-Phase Flow Cleaning of Endoscope Channels – Fundamentals of Cleaning

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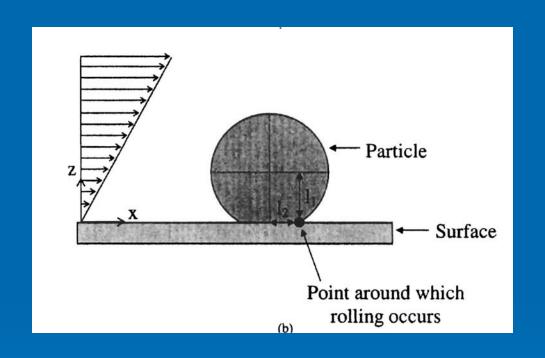
FDA Workshop

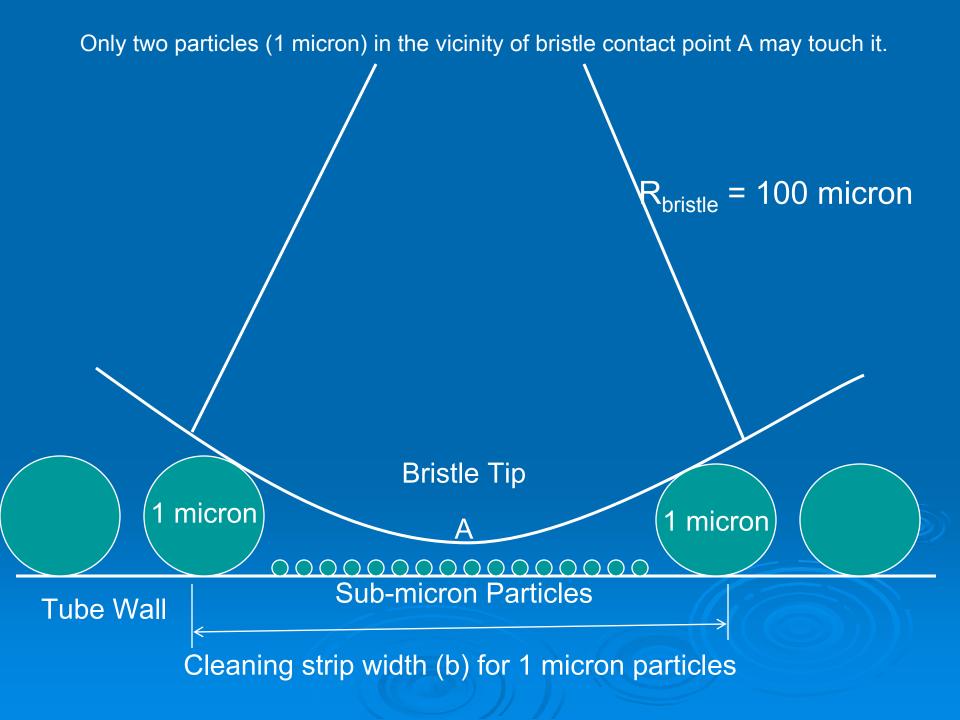
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#### Fundamentals of Narrow Channel Cleaning

- State-of-the-art of Channel Cleaning includes two steps:
  - a. Manual Pre-cleaning Brushing of Suction/Biopsy + Flushing of Air/Water
  - b. AER with Liquid Flow
- Physics of Brushing Assessment and Prediction
- Physics of Liquid Flow Cleaning
- Physics of Two-Phase Flow Cleaning
- Liquid Flow versus Two-Phase Flow
- Results of Two-Phase Flow Cleaning
- > Summary

## Physics and Mechanics of Brushing





# Predicted cleaning time with brushing for two particle size contaminants

$$t_{cl} = 0.86/E(a)^{0.5}$$
, sec

a, cm	E = 1	E = 0.2
10 <sup>-4</sup> (1µm)	86 (1.4 min)	430 (7.2 min)
10 <sup>-5</sup> (0.1µm)	272 (4.5 min)	1360 (22.7 min)

E = Efficiency factor (0 to 1)

a = Particle size

# Cleaning time with brushing to achieve certain log removal for two particle size contaminants

 $t_{cl} = 0.86a^{-0.5} (0.5 log removal) = 0.43a^{-0.5} log removal$ 

a, cm	Log removal 2	Log removal 4
10 <sup>-4</sup> (1µm)	86 (1.4 min)	172 (2.9 min)
10 <sup>-5</sup> (0.1µm)	272 (4.5 min)	544 (9.1 min)

E = Efficiency factor = 1

a = Particle size

#### Alfa, Degagne, Olson Am J Infect Control 1999

#### Flexible endoscopes after use (log<sub>10</sub> cfu)

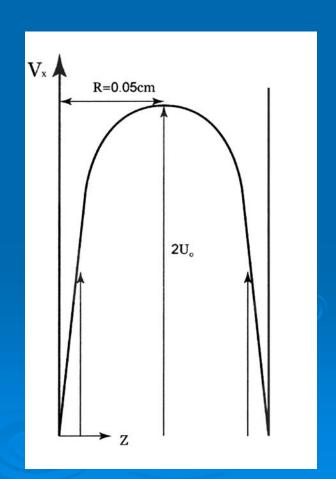
	Manual cleaning	before	after .
h	Bronchoscopes	4.0 - 7.3	3.8 - 5.7
,	Duodenoscopes	0 - 7.5	3.7 - 5.3
	Colonoscopes	5.7 - 9.5	3.2 - 4.6

## Physics of Liquid Flow Cleaning

Hydrodynamics of Liquid Flow in a Narrow Channel

Liquid flow detaches and removes a contaminant particle due to hydrodynamic detachment force (HDF).

HDF=Viscosity( $\eta$ ) x Shear Rate( $dV_x/dz$ )



> In the small vicinity of the endoscope wall, i.e.,

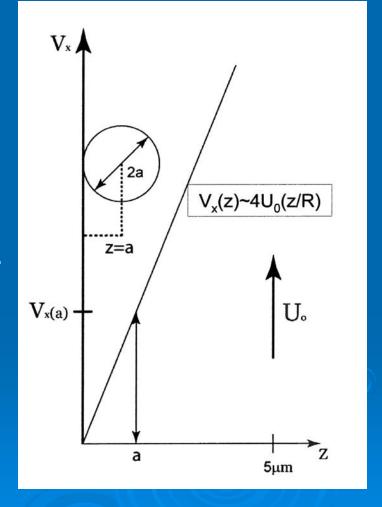
where z is the distance to the wall and R is the tube diameter, the parabolic profile is approximately linear, and the velocity distribution is:

$$V_x(z) = (4z/R)U_0$$

where U<sub>o</sub> is the mean velocity in the tube.

Accordingly, the mean velocity for the hydrodynamic flow around the attached particle is:

$$V_x(a) \sim (4a/R)U_0$$



Shear Rate =  $V_x(z)/z = 4U_0/R$  or in differential form:  $dV_x/dz$ 

The viscous force (F) is specified by the well-known Stokes equation:

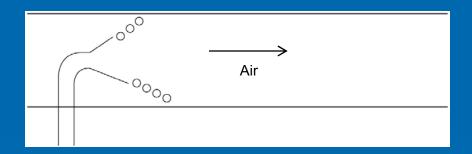
F = 
$$V_x(a)$$
 x Viscosity (η)  
F =  $6\pi\eta a V_x(a) = 24\pi\eta U_0 a^2/R$ 

The strong dependence on "a" shows that the hydrodynamic detachment force is strong for large particles and very weak for small particles. Accordingly, the liquid flow enables one to remove large particles, but it is not sufficient to eliminate submicron contaminants and bacteria when they are strongly adsorbed.

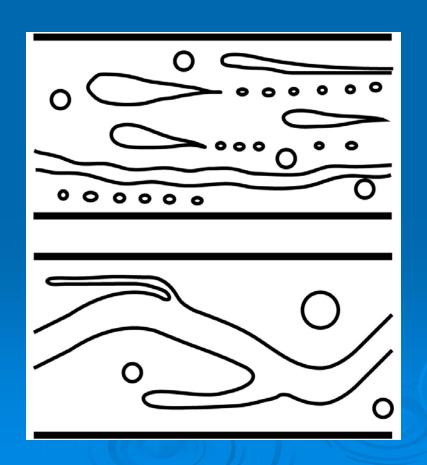
- The hydrodynamic detachment velocity  $V_x(a) = (4a/R)U_0$  is very small even for the not so small a ~ 1 micron, a/R ~  $10^{-3}$ .
- ➤ Current technology based on liquid flow does not allow us to achieve an increase in shear rate and HDF because the mechanical strength of the endoscope does not allow an increase in pressure to achieve larger U<sub>0</sub>.

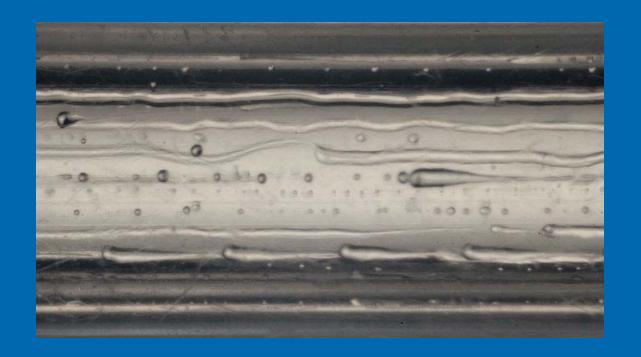
#### Two-Phase Flow Cleaning of Endoscope Channels

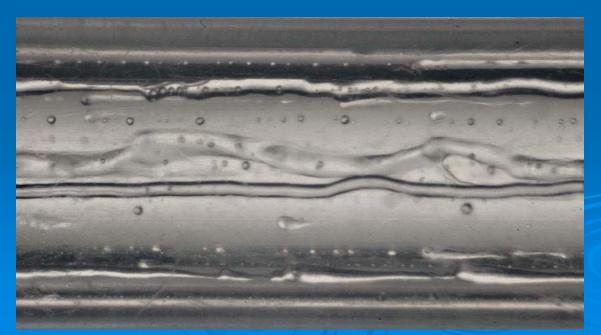
During our investigation of two-phase flow in hydrophobic narrow channels, we discovered a new hydrodynamic mode that can create shear stress orders of magnitude higher than the bulk shear generated by conventional liquid flow.



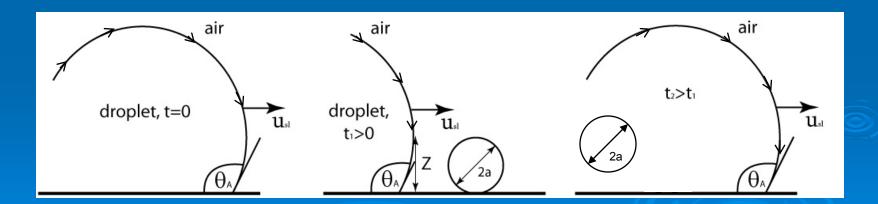
Two-phase flow is formed when a liquid stream is mixed with turbulent air flow along an endoscope channel while the ratio of water flow to air flow (WAVR) is very high, about 10<sup>3</sup>. After deposition on the Teflon wall, water slides and forms different kinds of sliding entities. Their images were obtained using high-speed video microscopy – one image per 4 milliseconds.







- > The front contact angle,  $\Theta_A$ , increases during sliding and the receding contact angle,  $\Theta_R$ , decreases.
- The air stream moves the droplet due to its viscous shear stress.
- The surface of the droplet moves towards its front pole and causes circulation inside the droplet.
- Although the distribution of velocity inside the droplet is complicated, its front surface moves downstream at the same velocity of the droplet as a whole, u<sub>sl</sub>.



#### Shear Rate with Two-phase Flow due to Sliding Droplet

$$V_x(z)/z \sim u_{sl}/z \sim u_{sl}/2a$$

### Liquid Flow versus Two-Phase Flow

Two Different Physics for Channel Cleaning

Shear Rate for Liquid Flow and Two-Phase Flow (Sliding Droplets)

Liquid Flow in Tube	Two-Phase Flow Sliding Droplet		
$(dV_x/dz)_{lf} \sim 4U_0/R$ (1)	(dV <sub>x</sub> /dz) <sub>sl</sub> ~ u <sub>sl</sub> /a (2)		

The advantage of sliding droplet cleaning (two-phase) compared to liquid flow cleaning is characterized by the ratio K in the table below.

#### K = <u>Shear Rate of Two-Phase Flow</u> Shear Rate of Liquid Flow

 $K = (dV_x/dz)_{sl}/(dV_x/dz)_{lf} = (u_{sl}/8U_0)(R/a)$  for Different Contaminant Sizes

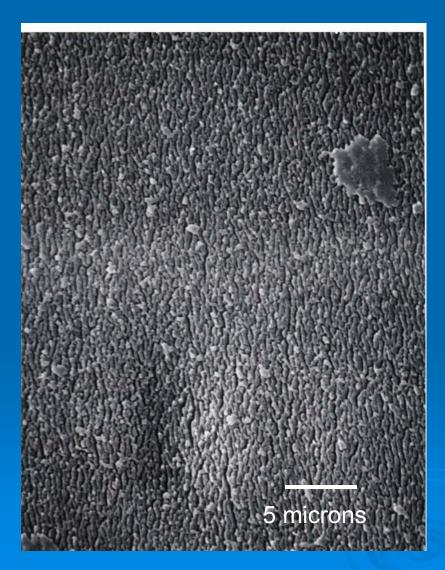
a, micron	1	0.1	0.01
K	10	100	1000
$(dV_x/dz)_{sl}$ , sec <sup>-1</sup>	5.10 <sup>4</sup>	5.10 <sup>5</sup>	5.10 <sup>6</sup>

 $u_{sl} \sim 5$  cm/sec (measured)

 $U_0 = 1 \text{ m/sec}$ 

# Results of Two-Phase Flow Cleaning

An electron microscopy image of sub-micron particles before treatment with two-phase flow (Magnification: x5000).



An electron microscopy image of sub-micron particles after treatment with two-phase flow (Magnification: x5000).



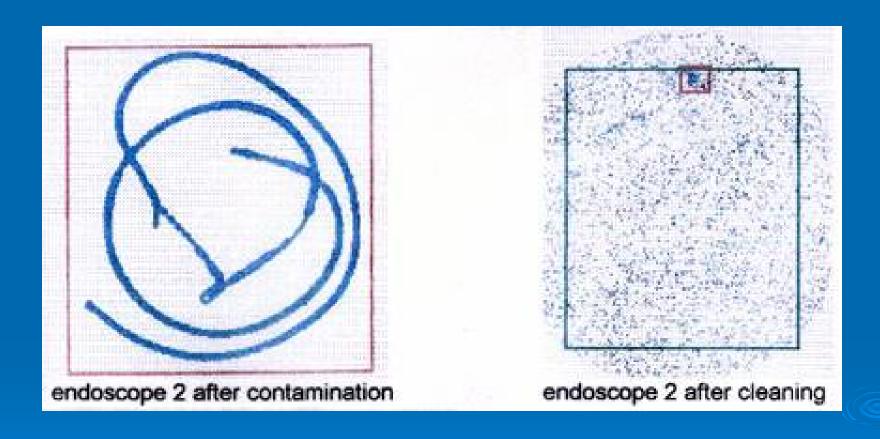
#### Radionuclide Method – Liquid Flow





Before After

#### **Radionuclide Method – Two-Phase Flow**



Before After

# Bioburden Removal by Two-Phase Flow (Suction/Biopsy Channel)

Test No.	Endoscope Model	L1 - Suction/Biopsy (Flush/Brush/Flush)					
		E. faecalis		P. aeruginosa		C. albicans	
		Inoculum	R.F.	Inoculum	R.F.	Inoculum	R.F.
		(Log10 cfu/ml)		(Log10 cfu/ml)		(Log10 cfu/ml)	
1	PENTAX® EG-2910	8.49	5.04	7.44	7.36	8.06	5.01
2	PENTAX® EG-2910	8.45	4.79	7.79	7.79	8.02	5.31
3	PENTAX® EG-2910	8.30	6.62	8.03	8.03	7.86	5.73
4	PENTAX® EG-2910	8.71	5.78	8.27	8.13	7.44	4.82
5	PENTAX® EG-2910	8.71	6.12	8.27	8.13	7.44	5.02
6	PENTAX® EG-2910	8.51	5.28	7.70	5.62	7.94	5.30
7	PENTAX® EG-2910	8.60	7.03	8.22	8.22	7.84	6.49
8	OLYMPUS® CF-Q160L	8.30	4.71	8.28	4.56	7.18	4.84
9	OLYMPUS® CF-Q160L	8.38	4.75	8.48	5.15	7.28	4.78
10	OLYMPUS® CF-Q160L	8.23	5.10	8.91	7.20	7.90	5.86
11	OLYMPUS® CF-Q160L	8.57	6.33				
	Average:	8.48	5.60	8.14	7.02	7.70	5.32
	Standard Deviation:	0.16	0.82	0.42	1.38	0.33	0.56

# Bioburden Removal by Two-Phase Flow (Air/Water Channels)

Test No.	Endoscope Model	L2 - Air/Water (Flush/Flush)					
		E. faecalis		P. aeruginosa		C. albicans	
		Inoculum	R.F.	Inoculum	R.F.	Inoculum	R.F.
		(Log10 cfu/ml)		(Log10 cfu/ml)		(Log10 cfu/ml)	
1	PENTAX® EG-2910	8.49	4.64	7.44	5.43	8.06	5.33
2	PENTAX® EG-2910	8.45	4.66	7.79	7.46	8.02	6.06
3	PENTAX® EG-2910	8.30	5.89	8.03	7.41	7.86	5.73
4	PENTAX® EG-2910	8.71	6.02	8.27	8.22	7.44	4.94
5	PENTAX® EG-2910	8.71	6.30	8.27	6.84	7.44	5.37
6	PENTAX® EG-2910	8.51	4.58	7.70	6.10	7.94	5.78
7	PENTAX® EG-2910	8.60	7.71	8.22	8.22	7.84	7.80
8	OLYMPUS® CF-Q160L	8.30	5.59	8.28	6.12	7.18	5.14
9	OLYMPUS® CF-Q160L	8.38	4.88	8.48	5.72	7.28	4.98
10	OLYMPUS® CF-Q160L	8.23	6.71	8.91	7.65	7.90	7.07
11	OLYMPUS® CF-Q160L	8.57	6.40		/		
	Average:	8.48	5.76	8.14	6.92	7.70	5.82
	Standard Deviation:	0.16	1.01	0.42	1.02	0.33	0.94

# Protein and TOC Residues Following Two-Phase Flow Cleaning of Soiled Lumens

Endoscope	Channel	Protein (μg/cm²)	TOC (μg/cm²)
OLYMPUS®	Suction / Biopsy	ND, ND, 0.02	0.06, 0.04, 0.05
TJF-160VF	Air / Water	0.02, ND, ND	0.05, ND, ND
	Elevator Wire	0.97, 0.46, 1.40	2.44, 1.17, 3.36
PENTAX® ED-3470	Suction / Biopsy	ND, 0.19, 0.04	ND, 0.15, 0.09
	Air / Water	0.08, 0.04, ND	0.23, 0.06, ND
OLYMPUS®	Suction / Biopsy	0.04, 0.12, ND	0.09, 0.03, ND
TJF-160VF	Air / Water	ND, ND, ND	0.01, ND, ND
PENTAX®	Suction / Biopsy	ND, ND, 0.10	ND, ND, ND
ED-3470	Air / Water	0.08, 0.14, ND	0.23, 0.25, ND

ND = Non-Detect / Below the Limit of Detection

## Summary

- 1. Physics of Liquid Flow Cleaning:
- > Shear Rate =  $dV_x/dz = 4U_0/R$
- $\rightarrow$  F = 24πηU<sub>0</sub>a<sup>2</sup>/R
- F is proportional to U₀a²/R
- 2. Liquid Flow Cleaning:
- Hydrodynamic Detachment Force (HDF) is strong for large particles
- HDF is very small for micron and sub-micron particles
- Experimental Results Average 3 to 4 log reduction (varies depending on source/publications)

## Summary (Cont.)

- 3. Two-Phase Flow Cleaning:
- Shear Rate = u<sub>sl</sub>/a
- F is proportional to u<sub>sl</sub>/a times viscosity
- Very effective in removing micron and sub-micron particles, including macromolecules
- ▶ Initial Results 5 to 8 log reduction (without brushing)
- 4. Brushing of Working Channels:
- Brushing + Flushing: 3 to 4 log reduction benchmark
- A long time is needed to achieve complete cleaning
- Not effective in removing micron and sub-micron particles
- 5. Contaminant nature, adhesion, testing methods and longterm cleaning effectiveness need further research

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